Abstract

A system for developing and implementing empirically derived algorithms to generate decision rules to predict subject noncompliance and fraud with research protocols in clinical trials allows for the identification of complex patterns of variables that detect or predict subject noncompliance and fraud with research protocol in the clinical trial. The present invention can also be used to monitor subject compliance with the research protocol to determine preferred actions to be performed. Optionally, the invention may provide a spectrum of noncompliance, from minor noncompliance needing only corrective feedback, to significant noncompliance requiring subject removal from the clinical trial. The algorithms and decision rules can also be domain-specific, such as detecting non-compliance or fraud among subjects in a cardiovascular drug trial, or demographically specific, such as taking into account gender or age which provides for algorithms and decision rules to be optimized for the specific sample of subjects being studied.